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K133544

510(k) Summary

Date: October 25th, 2013
Revised: 4th Febuary, 2014

Manufacturer:
PaloDEx Group Oy
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Contact person: Mr. Terho Turkumäki, Tel +358 50 320 9113

Trade Name:
OP300

Common Name:
Dental panoramic, cephalometric and cone beam computed tomography x-ray device

Classification Name:
x-ray, tomography, computed, dental (21 CFR § 892.1750, product code OAS)

Description:
The Orthopantomograph OP300 is an extra oral source dental x-ray device that is software-controlled which produces conventional digital 2D panoramic, cephalometric and TMJ x-ray images as well as digital x-ray projection images taken during cone beam rotations around a patient's head. The projection images are reconstructed to be viewed in 3D by a 3D viewing software.

Indication for Use:
The OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examination of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view. The device is operated and used by qualified healthcare professionals.

Intended Use:
The intended use of the OP300 is for dental radiographic examination of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view.

Summary of Technological Characteristics:
OP300 is substantially equivalent in design, composition and function to the current OP300 unit.

Concept		OP300 (K122018)	OP300 (Modified)
1.	Indications for use	The OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examination of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view. The device is operated and used by qualified healthcare professionals.	Same
2.	Imaging modes	Panoramic, Cephalometric, TMJ, 3D	Same
3.	X-ray source	3D mode: 90kV Pan mode: 57-90 kV Ceph mode: 60-90 kV kV accuracy: +/-5kV mA range: 3.2-16 mA 3D power mode: pulsed	Same
4.	Focal spot	0.5mm	Same
5.	Image detector(s)	CMOS Flat Panel + CMOS for pan/ceph imaging	Same
6.	3D imaging technique	Reconstruction from 2D images	Same
7.	3D's Field Of View	61 x 41 mm 61 x 78 mm	50 x 50 mm 61 x 78 mm 78 x 78 mm 78 x 150 mm 130 x 150 mm
8.	3D's total viewing angle	200 degrees	Same
9.	Pixel size	CMOS flat panel for 3D: 200 µm CMOS for panoramic imaging: 100 µm	Same
10.	Voxel size	80-350 µm	80-600 µm
11.	Reconstruction Software	Filtered Back Projection (FBP) or Algebraic Reconstruction Technique (ART)	Same
12.	3D's effective exposure time	2 - 20 sec	Same
13.	3D Reconstruction Time	1-3 min	Same
14.	Patient's Position	Standing and wheelchair	Same
15.	System footprint	H161-241cm x D1390cm x W97-193 cm	Same
16.	Weight	Pan/3D 205 kg Ceph 250 kg	Same

The differences between the Predicate Device OP300 (K122018), and the modified device are the following:

New panel and Field of Views: The small size 3D CMOS flat panel sensor (10x7) used in the Predicate Device OP300 (K122018) is replaced with a medium size CMOS flat panel sensor (12x12). This brings new bigger Field of View (FOV) sizes for the user. The new 3D programs to support the new FOV –sizes are: 50 x 50 mm, 61 x 78 mm (as in the Predicative Device), 78 x 78 mm, 78 x 150 mm and 130 x 150 mm.

Modified beam-limiting device is introduced to support the new FOV –sizes. Sliding aperture plate has been modified to consist of 3 apertures to allow the usage of new FOVs, instead of 1 aperture in the Predicative Device. Control principle remains the same as the predicate device.

The GUI software that is operated through the touch screen control panel has been modified to incorporate the changes to the imaging programs. Each new FOV –size has a new selection button in the updated GUI.

Following the ALARA (As Low As Reasonably Achievable) principle, a very low radiation dose mode for 3D imaging is introduced. The low radiation dose mode can be used for example in treatment follow-up cases where the most accurate image quality is not needed. As the radiation dose is lower, the voxel size needs to be bigger (lower resolution) in order to keep the dose per voxel in adequate level. Voxel size is an input parameter for the 3D reconstruction calculation.

Design verification and validation has been performed to ensure the safety and effectiveness of the device.

Performance (bench) Test Data:
In- house Performance (bench) testing has been conducted to compare the image quality and the sensor performance of the proposed OP300 and the predicate OP300 according to the recommendations in the "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices". As a result of the performance test it was concluded that there is no significant differences in image quality between the proposed and the predicate device.

The modified OP300 has been tested against FDA Recognized Consensus Standards (IEC60601-1:1988, IEC60601-1-2:2001, IEC 60601-1-3:1994, IEC60601-1-4:1996, IEC 60601-2-7:1998, IEC 60601-2-28:1993 and IEC 60601-2-32:1994). The standards used are the same standards as with the Predicate Device.

Images of an anthropomorphic phantom image for the 3D imaging mode were evaluated for the OP300 device and the predicate to demonstrate the modified device was capable of producing images without severe defects.

The modified OP300 has been successfully verified and validated to ensure the safety and effectiveness of the device.

Clinical Test Data:
Sample clinical images of patients were not used to support substantial equivalence of the OP300 device because the primary change to the imaging chain was a change in the detector size (other detector characteristics remained the same); the bench performance testing demonstrated that the new detector options had equivalent laboratory image quality performance to the predicate.

Conclusion:
Based upon the similar technological/performance characteristics to the predicate device and the successful validation of the OP300 software, the clinical performance of the OP300 is deemed to be substantially equivalent to the predicate devices.

The OP300 has been successfully verified and validated to ensure the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

PaloDex Group Oy
% Mr. Terho Turkumäki
QA&RA Manager
Nahkelantie 160
O4300 Tuusula
FINLAND

Re: K133544
Trade/Device Name: OP300
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: February 20, 2014
Received: February 24, 2014

Dear Mr. Turkumäki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133544

Device Name: OP300

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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